

## **EXHIBIT 11**

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND )  
COMPOUNDING PHARMACY, INC. ) MDL No. 2419  
PRODUCTS LIABILITY LITIGATION ) Dkt. No. 1:13-md-2419 (RWZ)  
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This Document Relates to: )  
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Suits Naming Specialty Surgery Center, )  
Crossville, PLLC )  
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**SPECIALTY SURGERY CENTER, CROSSVILLE, PLLC'S RESPONSES TO THE  
PLAINTIFFS' STEERING COMMITTEE'S FIRST SET OF INTERROGATORIES**

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Pursuant to Rules 26 and 33 of the Federal Rules of Civil Procedure, Specialty Surgery Center, Crossville, PLLC ("SSC"), by and through undersigned counsel, provides the following Responses to the Plaintiffs' Steering Committee's First Set of Interrogatories.

**INTERROGATORIES**

1. Explain how and why Specialty Surgery personnel decided to purchase compounded medications from the NECC, identify each and every individual involved in the decision, and describe each and every step in the decision making process.

RESPONSE:

**OBJECTION. This Interrogatory is overbroad.**

**Subject to and without waiving said objection, the Defendant states:**

The primary reason SSC began purchasing from the New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center ("NECC") was NECC's ability to offer 5 mL, single-dose vials of Omnipaque, and preservative-free methylprednisolone acetate ("MPA").

In 2005, Jean Atkinson, RN, SSC's nursing director, met Mario Giamei, an employee of Medical Sales Management and an NECC sales representative, at a Freestanding Ambulatory Surgery Center Association ("FASCA") conference. At the time, SSC was dealing with a shortage of Omnipaque, and Ms. Atkinson decided to purchase Omnipaque from NECC. Ms. Atkinson remembers very little about her interactions with NECC in 2005, but SSC records show that on or about October 7 and December 2, 2005, SSC purchased NECC Omnipaque. There were no problems with SSC's orders of Omnipaque from NECC. After receiving the two orders, SSC did not purchase NECC medications again until 2012.

In September 2011, Ms. Atkinson saw Mr. Giamei at another FASCA conference in Gatlinburg, Tennessee. Mr. Giamei asked Ms. Atkinson why SSC had not ordered any Omnipaque from NECC lately, and they spoke briefly.

Prior to purchasing from NECC, Ms. Atkinson ordered, and Dr. Lister used, MPA purchased from either Besse Medical or CuraScript, Inc., depending on availability and price. The MPA purchased from Besse and CuraScript contained a preservative. Dr. Lister read some literature reporting that a woman developed arachnoiditis after receiving an epidural steroid injection of MPA with preservative. Dr. Lister decided that he wanted look into using preservative-free MPA. He asked Ms. Atkinson to see if she could obtain it.

Ms. Atkinson attempted to purchase preservative-free MPA from Besse Medical, CuraScript, Inc. and Physician Sales and Services, but none of them offered preservative-free MPA.

Additionally, in early 2012, Dr. Lister either listened to a Continuing Medical Education ("CME") lecture or attended a meeting during which the CDC recommendation that health care facilities use single-dose vials was discussed. It was also mentioned that the CDC permitted companies to break down larger vials into single-dose vials. Afterward, Dr. Lister discussed with Ms. Atkinson using multi-dose vials on a single patient or finding a company that sold single-dose vials.

Ms. Atkinson recalled that NECC offered single-dose vials of Omnipaque and preservative-free MPA, so she discussed purchasing both medications from NECC with Dr. Lister. She informed Dr. Lister that SSC had purchased Omnipaque from NECC in the past and had no problems. Ms. Atkinson told Dr. Lister it was her understanding that NECC would break down larger vials into single-dose vials. Dr.

Lister agreed to purchase from NECC and asked Ms. Atkinson to ensure it was licensed.

Ms. Atkinson called Mr. Giamei to ask about purchasing. Mr. Giamei stopped by the center in early July 2012 to drop off advertising information and meet with Ms. Atkinson. Mr. Giamei gave Ms. Atkinson a copy of NECC's Tennessee Board of Pharmacy license<sup>1</sup> and discussed NECC's state-of-the-art compounding process with Ms. Atkinson, including NECC's adherence to USP 797.

Mr. Giamei and Ms. Atkinson also discussed the CDC recommendation that facilities use single-dose vials for injectable medications. Mr. Giamei told Ms. Atkinson that NECC could break larger vials of Omnipaque down into 5 mL vials to lessen wastage and "keep CDC off your [SSC's] doorstep."

After their meeting, Ms. Atkinson conducted background research regarding USP 797 on the internet.

On July 10, 2012, Mr. Giamei dropped off an NECC credit application and a blank order form with Diane Austin, an SSC employee. He also emailed Ms. Atkinson a blank order form, a CDC position paper regarding the use of single-use vials for multiple patients, and an article from the End Depo Now Campaign discussing the use of preservatives in intrathecal and epidural administration.<sup>2</sup>

Ms. Atkinson briefly recounted her recent meeting with Mr. Giamei to Dr. Lister and mentioned the CDC position paper. She advised Dr. Lister that she believed NECC could supply the Omnipaque but told him it would be more expensive. Dr. Lister instructed Ms. Atkinson to go ahead and purchase the Omnipaque from NECC because it would be single-use.

After reviewing the NECC order form from Mr. Giamei, Ms. Atkinson called Mr. Giamei to ask why NECC needed patient names. Mr. Giamei stated that the names were required by state pharmacy guidelines. He told Ms. Atkinson that SSC could provide 20 or 25 patient names and NECC would dispense four or five vials per patient. Ms. Atkinson told Mr. Giamei that a single patient would likely not receive all four or five vials. Mr. Giamei stated that was fine because NECC only needed the names of SSC patients. Ms. Atkinson told Mr. Giamei that she wanted to speak with SSC's management

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<sup>1</sup> Ms. Atkinson is not certain that she obtained the copy of NECC's Tennessee Board of Pharmacy license at this particular meeting, but she is certain she obtained it prior to purchasing.

<sup>2</sup> All emails between Ms. Atkinson and Mr. Giamei in SSC's possession are being produced with SSC's Responses to the PSC's First Set of Requests for Production and speak for themselves.

company, Calisher & Associates, before sending the patient names because she had never been asked to provide patient names by other medication suppliers.

Ms. Atkinson called Gina Calisher at Calisher & Associates, and Ms. Calisher instructed Ms. Atkinson to request a copy of the state pharmacy guidelines applicable to NECC. Ms. Atkinson believes that Calisher & Associates also instructed SSC's Administrator, Kim Bowlin,<sup>3</sup> to have NECC execute a "Business Associate Agreement," as SSC did with all vendors.<sup>4</sup>

Ms. Atkinson relayed the substance of her discussions with Calisher & Associates and Mr. Giamei regarding the patient names to Dr. Lister. Dr. Lister told Ms. Atkinson not to do anything she felt uncomfortable doing and advised her to follow Calisher & Associates' advice.

On July 11, 2012, Ms. Atkinson and Mr. Giamei exchanged emails regarding the pharmacy guidelines applicable to NECC. Mr. Giamei called Ms. Atkinson and offered to meet to discuss the order form on July 12.

On July 12, 2012, Ms. Atkinson emailed Mr. Giamei to cancel the meeting due to a high volume of patients at SSC that day. Mr. Giamei responded via email, referring Ms. Atkinson to Title 63 of the Tennessee Code. Ms. Atkinson looked up Title 63 on the internet but had trouble locating the applicable provision. She called Mr. Giamei for clarification and informed him that Calisher & Associates wanted her to obtain a copy of the applicable guidelines before ordering the medication using patient names. Mr. Giamei promised to talk to someone at NECC and get back to her. Mr. Giamei also sent Ms. Atkinson a follow-up email confirming their call.

Later that day, Ms. Atkinson and Mr. Giamei exchanged emails clarifying what patient information NECC actually needed. Ms. Atkinson also exchanged emails with Ms. Calisher regarding the applicable statutes/guidelines.<sup>5</sup> That afternoon, Mr. Giamei emailed Ms. Atkinson and asked her to call him. Ms. Atkinson does not specifically recall whether or not she did so.

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<sup>3</sup> Ms. Bowlin was employed by Calisher & Associates.

<sup>4</sup> The signed "Business Associate Agreement" is being produced with SSC's Responses to the PSC's First Set of Requests for Production.

<sup>5</sup> All emails between SSC and Calisher & Associates referenced in SSC's response to Interrogatory 1 are being produced with SSC's Responses to the PSC's First Set of Requests for Production and speak for themselves.

Carey Fenton, a sales representative from US Compounding, a compounding pharmacy in Conway, Arkansas, visited SSC during this timeframe. Ms. Atkinson asked Mr. Fenton if it was normal for compounding pharmacies to request a list of names. Mr. Fenton called back later in the day and told Ms. Atkinson that it was normal for compounders to do so.

Ms. Atkinson conducted additional internet research and located the Tennessee Board of Pharmacy regulations. She sent an email to Ms. Calisher referencing the standards. Afterward, Ms. Calisher called either Ms. Atkinson or Ms. Bowlin and said that SSC could proceed with purchasing from NECC using patient names.

Ms. Atkinson filled out the order form using the names of patients scheduled to come in for pain management procedures with Dr. Lister over the next few days, and Dr. Lister signed the form. Ms. Atkinson faxed the form and credit application to NECC on July 12, 2012, and emailed Mr. Giamei to let him know she had done so. Mr. Giamei responded via email to let her know he would "keep an eye out for it."

On July 16, 2012, Ms. Atkinson emailed a blank "Business Associate Agreement" to Mr. Giamei for execution by NECC. According to the signature, Barry Cadden signed the "Business Associate Agreement" on July 17, 2012. Mr. Giamei emailed the signed copy to Ms. Atkinson on July 18, 2012, and asked her to return a fully-executed copy once SSC signed it. Ms. Bowlin signed the agreement on behalf of SSC.

2. Identify each communication (including face-to-face, telephone, email, or other communications) between NECC (including its agents, employees or representatives) and Specialty Surgery (including its agents, employees or representatives). For each communication identified, please provide the following information:

- a) the names, job titles, and contact information for each person involved in the communication;
- b) the date, time, length, mode and location of each communication or discussion;
- c) whether any notes, memoranda, recordings, writings or other records were kept of any of those conversations or communications; and
- d) state as specifically as possible what each party to the communication or conversation said and state what actions Specialty Surgery took, if any, as a result of each communication or conversation.

**RESPONSE:**

**OBJECTION.** This interrogatory is overbroad in timeframe and scope. Subject to and without waiving said objection, the following are communications with NECC not covered by the Response to Interrogatory 1:

On or about July 17, 2012, SSC received the MPA and Omnipaque from its first order from NECC.

On August 13, 2012, Ms. Atkinson ordered 120 vials of MPA from NECC via fax.

On or about August 15, 2012, SSC received the shipment from its August 13 order.

On September 26, 2012, SSC received a Voluntary Product Recall letter via fax.

On September 27, 2012, Ms. Atkinson filled out NECC's Voluntary Product Recall Response Form, which NECC had included with its initial fax, and faxed it back to NECC. Ms. Atkinson believes that Ms. Bowlin spoke with someone at NECC who instructed her to go online

to print a return label from FedEx's website to use to return the recalled medication.

On October 4, 2012, SSC received another Voluntary Product Recall fax from NECC recalling additional medications.

On or about October 6, 2012, SSC received a letter from NECC dated October 6, 2012 voluntarily recalling ALL NECC products.

On October 16, 2012, SSC sent a letter to NECC revoking acceptance of the NECC MPA and notifying NECC that it had breached the warranties of merchantability and fitness for the medication.

For additional information regarding SSC's response to the recall, see Response to Interrogatory 19 below and SSC's Responses to the PSC's First Set of Requests for Production, which include the documents referenced in this Response.

3. Please list the date, location, and attendees present at each and every meeting (business or social) between or among NECC (including its agents, employees or representatives) and Specialty Surgery (including its agents, employees or representatives).

RESPONSE:

See Response to Interrogatory 1.

4. List each and every communication (including emails, conversations, meetings, memos, etc.) that occurred before October 1, 2012 between you, on the one hand, and Dr. Lister, on the other hand, regarding compounding pharmacies, acquiring medication from compounding pharmacies, NECC (including its agents and representatives), and/or the acquisition of injectable steroids. For each such communication, please specify the parties to the communication, the date of the communication, the mode of the communication, and the content of the communication.

RESPONSE:

**OBJECTION.** This Interrogatory seeks irrelevant information that is not reasonably calculated to lead to the discovery of admissible evidence. Magistrate Judge Boal has already ruled that information regarding health care providers' procurement of MPA or MPA equivalents from any supplier other than NECC is irrelevant [Dkt. 572]. Additionally, the request is overbroad, unduly burdensome, and seeks information that is protected from discovery by the work-product doctrine, attorney-client privilege, the Tennessee Peer Review Law of 1967, Tenn. Code Ann. § 63-6-219, the Tennessee Patient Safety and Quality Improvement Act of 2011, Tenn. Code Ann. §§ 63-1-150, 68-11-272, and/or HIPAA. Additionally, the Request for Production contains no time limitation, and, as such, is overbroad and unduly burdensome.

Subject to and without waiving said objections, several years before 2012, SSC purchased phenol from VitalCare, a local compounder, on a couple of occasions for general office use. Dr. Lister does not recall the specifics of any conversations regarding the phenol. Dr. Lister also recalls purchasing ethyl-alcohol from a different compounding pharmacy, but does not recall the name of the pharmacy. For further response, see Response to Interrogatory 1.

5. How much did Specialty Surgery pay per vial for MPA that it purchased from NECC in 2012?

RESPONSE:

See invoices included with SSC's Responses to the PSC's First Set of Requests for Production.

6. Please list every company, manufacturer, compounder or distributor from whom Specialty Surgery purchased any steroid used in epidural steroid injections since January 1, 2008. Please specify the date of each purchase, the quantity ordered, and how much Specialty Surgery paid for each vial of injectable steroid.

RESPONSE:

**OBJECTION.** This Interrogatory seeks irrelevant information that is not reasonably calculated to lead to the discovery of admissible evidence. Magistrate Judge Boal has already ruled that information regarding health care providers' procurement of MPA or MPA equivalents from any supplier other than NECC is irrelevant [Dkt. 572]. Additionally, the request is overbroad and unduly burdensome.

Subject to and without waiving said objections, SSC is producing all documents from Besse Medical and CuraScript, Inc., its two other suppliers of MPA, with its Responses to the PSC's First Set of Requests for Production.<sup>6</sup> The invoices from Besse Medical and CuraScript, Inc. reflect dates and amounts of MPA purchased.

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<sup>6</sup> The documents from Besse Medical and CuraScript, Inc. also contain information regarding some of SSC's purchases of other injectable steroids, but these injectable steroids were not used in epidural steroid injections.

7. Describe each and every action that Specialty Surgery took in order to ensure that MPA injected into patients was safe and free from contaminants.

RESPONSE:

**OBJECTION.** This Interrogatory is overbroad. For an explanation of how SSC went about purchasing from NECC, see the response to Interrogatory 1. That process complied with the recognized standard of acceptable professional practice.

Subject to and without waiving said objection and without limitation to further supplementation through written responses, witness testimony, and expert discovery, as discovery progresses, SSC states:

**Ms. Atkinson complied with the recognized standard of acceptable professional practice for drug procurement by:**

1. Speaking with Mr. Giamei regarding NECC,
2. Reviewing materials provided by Mr. Giamei regarding the sterility of NECC's compounding processes,
3. Obtaining a copy of NECC's Tennessee Board of Pharmacy license,
4. Reviewing Tennessee Board of Pharmacy regulations,
5. Consulting with Dr. Lister,
6. Consulting with Calisher & Associates,
7. Consulting with Carey Fenton from US Compounding, and
8. Performing background research regarding USP 797.

After purchasing, SSC checked the expiration dates on all medication on a monthly basis to ensure that no expired medications were used. During procedures, SSC also checked expiration dates. SSC had used NECC in 2005 without incident and had received prompt and professional delivery and customer service.

Finally, the injections were performed in compliance with the recognized standard of acceptable professional practice for maintaining sterility.

8. Describe in detail every gift, sample, incentive, promotion, thank you gift, and/or discount that Specialty Surgery (or anyone associated with it) ever received from NECC (including its agents, employees or representatives) or any wholesaler or distributor of any injectable steroid.

RESPONSE:

**OBJECTION.** This Interrogatory is overbroad and seeks irrelevant information that is not reasonably calculated to lead to the discovery of admissible evidence. Whether SSC received a discount from suppliers other than NECC is irrelevant to the claims forming the basis of the Plaintiffs' Complaints and not reasonably calculated to lead to the discovery of admissible evidence. Magistrate Judge Boal has already ruled that information regarding health care providers' procurement of MPA or MPA equivalents from any supplier other than NECC is irrelevant [Dkt. 572]. Further, to the extent this Interrogatory requests information regarding anyone "associated with" SSC, it is overbroad and unduly vague, and the Interrogatory should be directed to those individuals if they are not members, employees, or former employees of SSC.

Subject to and without waiving said objections, SSC may have received a discount from CuraScript, Inc. and Besse Medical through MedAsset, a group purchasing organization of which SSC was a member. SSC has made a reasonable inquiry but the information known and readily attainable does not permit SSC to state the amount of the discount or to state whether the discount applied to MPA. If SSC received a discount, the discounted prices are reflected in the invoices SSC is producing with its Responses to the PSC's First Set of Requests for Production.

9. Identify each Specialty Surgery employee during 2012 by name and job title, and state whether each such employee is still employed by the company. Please also give a general description of the duties of each such person.

RESPONSE:

**OBJECTION.** This Interrogatory is overbroad to the extent it requests a general description of job duties unrelated to the purchase of MPA from NECC. SSC describes relevant job duties in Response to Interrogatory 11, below.<sup>7</sup>

**Subject to and without waiving said objections, SSC states:**

Kim Bowlin	Administrator <sup>8</sup>
Jean Atkinson	RN, Director of Nursing
Sheila Goney	LPN
Karen Laws	LPN
Michelle Phillips	RN
Patricia Richards	RN
Kristine McKinney	RN
Kristie Wyatt	CST
Lisa Disney	CST
Ann Hatfield	CST
Diane Austin	ST
Brittany Schubert	Front Desk Clerk
Sandra Turner	Receptionist
Christy Kerley	Coding
Leanne Sietsema	Patient Accounts Receivables

**SSC currently has no employees.**

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<sup>7</sup> SSC's list of job descriptions is being produced with SSC's Responses to the PSC's First Set of Requests for Production.

<sup>8</sup> Ms. Bowlin was employed by Calisher & Associates, Inc. but is listed here for the sake of completeness.

10. Please identify all individuals having an ownership interest in Specialty Surgery from 2012 to the present:

- a) the person's name, job title and contact information;
- b) a description of the duties or functions performed; and
- c) a statement of whether the person continues to maintain an ownership interest in Specialty Surgery Center.

RESPONSE:

**OBJECTION.** This Interrogatory is overbroad to the extent it requests a general description of job duties unrelated to the purchase of MPA from NECC. SSC describes relevant job duties in Response to Interrogatory 11, below.

**Subject to and without waiving said objections, SSC states:**

**The following physicians were members of SSC and served on the board and Medical Executive Committee prior to its dissolution in 2014:**

**Kenneth Lister, MD  
Jon Simpson, MD  
Mark Fox, MD  
Donathan Ivey, MD  
Mark Lee, MD  
Robert Nichols, MD  
Susan Pick, MD.**

All individuals listed can be contacted through counsel for SSC. Dr. Simpson was the medical director of SSC in 2012. Otherwise, the members did not have specific job titles.

11. Please identify every employee or agent of Specialty Surgery who performed any duties or functions for Specialty Surgery related to the purchasing of epidural steroid injections, including, but not limited to MPA, and for each such person, please state:

- a) the person's name, job title and contact information;
- b) a description of the duties or functions performed; and
- c) a statement of whether the person continues to be employed by or affiliated with Specialty Surgery.

**RESPONSE:**

**OBJECTION.** This Interrogatory seeks irrelevant information that is not reasonably calculated to lead to the discovery of admissible evidence. Magistrate Judge Boal has already ruled that information regarding health care providers' procurement of MPA or MPA equivalents from any supplier other than NECC is irrelevant [Dkt. 572].

**Subject to and without waiving said objections:**

**Kenneth Lister, MD** – Dr. Lister participated in the decision to purchase from NECC.

**Jean Atkinson, RN** – Ms. Atkinson helped select suppliers of MPA and typically ordered it. She participated in the decision to purchase from NECC.

**Diane Austin** – Ms. Austin placed orders for medications when Ms. Atkinson was unavailable.

**Kim Bowlin** – Ms. Bowlin was responsible for processing invoices.

**Calisher & Associates** owners, managers, or employees, including, but not limited to, Gina Calisher, Ron Calisher, Kevin Calisher, and Brandon Kowarsky – Calisher & Associates was required to contract for the purchase of pharmaceuticals for SSC and implement appropriate policies and procedures. Ms. Atkinson consulted with Calisher & Associates from time to time regarding the purchase of pharmaceuticals, including as described above.

12. Explain in detail Specialty Surgery's policies and procedures regarding the purchase of medications.

RESPONSE:

**OBJECTION.** This Interrogatory is overbroad and seeks irrelevant information that is not reasonably calculated to lead to the discovery of admissible evidence. Magistrate Judge Boal has already ruled that information regarding health care providers' procurement of MPA or MPA equivalents from any supplier other than NECC is irrelevant [Dkt. 572].

Subject to and without waiving said objections, SSC is producing its "Pharmaceutical Services" policy with its Responses to the PSC's First Set of Requests for Production. In addition to the written policy, SSC's common practice, while not a written policy, for purchasing medications is described below:

If Ms. Atkinson decided to purchase medication from a new supplier, she generally followed the process described for NECC in Response to Interrogatory 1. Ms. Atkinson generally conferred with the company's representative and reviewed materials provided by the company. She also obtained pricing and product information from the company. Once she decided that it was in SSC's and SSC's patients' best interests to begin purchasing from the company, Ms. Atkinson verbally advised the physician(s) who used the product of her intention and obtained his/her/their approval.

When SSC's supply of a given medication began to get low, Ms. Atkinson (or Ms. Austin when Ms. Atkinson was not available) placed an order for the medication.

13. Please describe in detail all systems, policies and procedures used at Specialty Surgery in order to evaluate compounding pharmacies from which it purchased medications.

RESPONSE:

**OBJECTION.** This Interrogatory is overbroad and seeks irrelevant information that is not reasonably calculated to lead to the discovery of admissible evidence. Magistrate Judge Boal has already ruled that information regarding health care providers' procurement of MPA or MPA equivalents from any supplier other than NECC is irrelevant [Dkt. 572].

**Subject to and without waiving said objections, SSC does not have a written policy specifically addressing compounding pharmacies. The process by which SSC selected new suppliers is described in detail in the preceding Responses.**

14. Please describe in detail (including names and dates) the extent to which anyone associated with Specialty Surgery consulted with any pharmacist or hospital pharmacy department regarding whether to purchase medications from NECC in particular or compounding pharmacies in general.

RESPONSE:

**OBJECTION.** This Interrogatory is overbroad and seeks irrelevant information that is not reasonably calculated to lead to the discovery of admissible evidence. Magistrate Judge Boal has already ruled that information regarding health care providers' procurement of MPA or MPA equivalents from any supplier other than NECC is irrelevant [Dkt. 572]. This Interrogatory also seeks information privileged from discovery by the Tennessee Patient Safety and Quality Improvement Act of 2011, Tenn. Code. Ann. §§ 63-1-150, 68-11-272.

**Subject to and without waiving said objections, the acceptable standard of professional practice did not require SSC to consult with a pharmacist or hospital pharmacy department regarding whether to purchase medications from NECC. All steps taken by SSC prior to purchasing from NECC are described in detail in the preceding Responses.**

15. Does Specialty Surgery contend that any other person or entity is responsible or caused the injuries and deaths that are the subject of this litigation? If so, identify each such person or entity and state the factual basis for a contention that any other person or entity was responsible for or caused the injuries and deaths forming the basis of this litigation.

RESPONSE:

**See Comparative Fault section of SSC, et. al.'s Answer to the Master Complaint at Dkt. 1456 and the comparative fault section of any amended answer filed by SSC in this litigation in the future.**

16. State the name and address of any expert witness who you expect to call at the trial of this cause, and for each and every such expert witness, please provide all information and material required by Fed. R. Civ. Pro. 26(a)(2)(B).

RESPONSE:

**SSC will make the required disclosures in accordance with any Court-ordered schedule and/or the Federal Rules of Civil Procedure.**

17. State the name and address of any person who you expect to offer opinion testimony at the trial of this case, irrespective as to whether such individual is an "expert" as defined by Fed. R. Civ. Pro. 26. With respect to each such individual, please state their name and address, the subject matter on which the individual is expected to testify, the substance of the facts and opinions to which the individual is expected to testify and a summary of the grounds for each opinion.

RESPONSE:

**SSC's attorneys have not yet determined what witnesses they intend to call at trial. This response will be supplemented in compliance with any applicable scheduling order and the Federal Rules of Civil Procedure.**

18. State the full name, address, telephone number, job title and employer of each and every person believed by Specialty Surgery to have knowledge of facts regarding the claims asserted in this litigation, any defenses thereto, and/or any issues germane to this litigation. Please include any person believed to have knowledge of rebuttal or impeachment evidence, and for each person listed, please identify the subject matter of their knowledge and provide a brief description of their knowledge.

RESPONSE:

**OBJECTION.** This Interrogatory is overbroad, unduly burdensome, duplicative, and seeks information protected from discovery by the work-product doctrine and attorney-client privilege. The Plaintiffs can readily and easily obtain this information from (1) SSC's Rule 26(a)(1) initial disclosures and discovery responses; (2) the initial disclosures and discovery responses of other parties; (3) the public reports regarding the investigation of NECC and the other Defendants; and (4) the Plaintiffs' medical records.

19. When and how did you (or your agents) become aware of the recent fungal meningitis outbreak?

RESPONSE:

On Wednesday, September 26, 2012, at 3:58 pm, SSC received a fax from NECC voluntarily recalling 220 vials of lot 06292012@26, which had been shipped to SSC on July 16, 2012, and August 14, 2012. Ms. Atkinson believes that Ms. Bowlin placed the fax on Ms. Atkinson's desk before leaving for the day.

On Thursday, September 27, 2012, Ms. Atkinson arrived at work around 6:30 am to discover the fax on her desk. SSC quarantined the remaining 31 vials and cancelled pain management procedures scheduled that day due to the lack of steroid. Ms. Atkinson called Dr. Lister and informed him of the cancellation of the day's appointments due to the recall.

At around 7:30 am on Friday, September 28, 2012, Dr. Marion Kainer, Director of the Tennessee Department of Health's Healthcare Associated Infections & Antimicrobial Resistance Program, called SSC and informed Ms. Atkinson that there were cases of meningitis possibly associated with the NECC MPA. Dr. Kainer instructed SSC to contact patients and check on their status, but not to mention meningitis or the recall. Dr. Kainer dictated a short script to Ms. Atkinson for SSC to use when contacting patients. SSC staff members began calling patients that day using the script from Dr. Kainer. They reached approximately 70% of patients who received the NECC MPA; none reported any problems. At around 4:00 pm, Dr. Kainer called to check on the status of notifying patients. Ms. Atkinson informed her of the results. Dr. Kainer instructed Ms. Atkinson to attempt to reach the remaining patients on Monday, October 1, 2012.

On Sunday, September 30, 2012, Dr. Lister received a phone call from Martha Carter, MD to inform him of the meningitis "cluster."<sup>9</sup> Ms. Atkinson received a similar phone call from Dr. Carter the same day. Dr. Lister called Ms. Atkinson that evening and instructed her to have the SSC staff notify patients the following day, Monday, October 1, 2012, using the new script from the CDC. The new script included reference to the recall and meningitis.

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<sup>9</sup> Dr. Carter is an anesthesiologist who formerly worked at SSC. She also previously worked with Donald Jones, MD before he began working at PCA Pain Care Center, Oak Ridge. The Department of Health sent Dr. Carter notification of the cluster in an attempt to contact Dr. Jones. Dr. Carter called Dr. Lister and forwarded him the email, which included a new script for contacting patients from the CDC.

Beginning on October 1, 2012, SSC began calling patients and reached almost all of the patients who may have received the recalled MPA.<sup>10</sup> On October 2, 2012, they reached all but two of the remaining patients. On October 5, 2012, SSC received confirmation that the remaining two patients had been reached by the Tennessee Department of Health. SSC sent letters to patients notifying them, again, of the recall. SSC sent letters to physicians or physician groups who referred patients to SSC for epidural steroid injections to alert them to the recall and outbreak. Dr. Lister assisted in notifying patients and also contacted physicians or physician groups who referred patients to SSC for epidural steroid injections to alert them to the recall and outbreak and provided them with a list of patients they had referred to SSC who may have received the recalled MPA.

20. When and how did you (or your agents) become aware that you had received contaminated medication from NECC and how did you respond to that information?

RESPONSE:

**See SSC's Response to Interrogatory 19.**

21. Describe when and how you began contacting patients after learning of the fungal meningitis outbreak.

RESPONSE:

**See Response to Interrogatory 19.**

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<sup>10</sup> On October 1, SSC attempted to reach all patients who may have received the NECC, not just those who they were unable to reach on September 28.

22. Describe in detail any interruption in business operations of Specialty Surgery Center that occurred as a result of the fungal meningitis outbreak by identifying the nature of the interruption (i.e. whether Specialty Surgery closed), the duration of the interruption, and the date upon which Specialty Surgery resumed normal operations.

RESPONSE:

**OBJECTION.** This Interrogatory seeks information that is irrelevant and not reasonably calculated to lead to the discovery of admissible evidence.

Subject to and without waiving said objections, on September 27, 2012, Dr. Lister stopped seeing pain management patients. However, because SSC's practice was not limited to pain management, SSC remained open and continued to see patients. On or about October 23, 2012, after receiving a letter from the Tennessee Department of Health dated October 16, 2012, Dr. Lister began performing pain management procedures for patients who did not receive MPA from any of the three recalled lots.

23. Please explain in detail all actions that you took in order to preserve evidence in connection with the fungal meningitis outbreak.

RESPONSE:

All SSC staff members were instructed on several occasions to preserve anything relevant to the meningitis outbreak.

24. Describe in complete detail the business structure of Specialty Surgery including but not limited to:

- a) provide the names and job title of each officer of Specialty Surgery;
- b) provide the name of each manager of Specialty Surgery;
- c) provide the name of each owner or member of Specialty Surgery;
- d) identify all contracts, agreements, cost-sharing arrangements, profit-sharing arrangements, and patient referral arrangements existing between or among Specialty Surgery and any other health care provider;
- e) describe in detail all financial arrangements that presently exist or have previously existed between or among Specialty Surgery and any other health care provider; and
- f) identify and describe every lease for space occupied by Specialty Surgery.

RESPONSE:

**OBJECTION.** This Interrogatory seeks information that is irrelevant and not reasonably calculated to lead to the discovery of admissible evidence.

Subject to and without waiving said objections, see SSC's Response to Interrogatory 10. SSC is producing the following contracts with its Responses to the PSC's First Requests for Production:

- 1) SSC's Shared Services Agreements with Dr. Lister
- 2) SSC's Statements of Interest SSC, including an agreement transferring part of Vincent Longobardo, MD's interest in SSC to Dr. Lister
- 3) A Business Associate Agreement between SSC and Dr. Lister
- 4) A confidentiality agreement between SSC and Dr. Lister
- 5) SSC's Operating Agreement
- 6) SSC's Asset Purchase Agreement with Cumberland Medical Center

- 7) SSC's lease for office space from Jon A. Simpson Properties
- 8) SSC's Limited Use Agreement with Jon A. Simpson, MD.

Ron Calisher, Gina Calisher, and Kim Bowlin of Calisher & Associates were the individuals from Calisher & Associates who were primarily responsible for managing SSC pursuant to the management contract. SSC's members participated in the management of SSC as board members.

SSC entered into a contract for anesthesia services with Cumberland Anesthesia Group effective January 1, 2011. SSC terminated the contract effective February 4, 2013. None of the anesthesiologists with Cumberland Anesthesia Group performed pain management procedures at SSC.

SSC entered into a contract for anesthesia services with AHP of East Tennessee, PLLC effective February 4, 2013. None of the anesthesiologists with AHP performed pain management procedures at SSC.

Any other contracts or financial arrangements that existed between SSC and any other health care provider are unrelated to SSC's pain management practice and, accordingly, are irrelevant to these cases.

25. Please explain how Specialty Surgery charged patients and/or their insurers for epidural steroid injections in 2012. Specifically, list the rate that Specialty Surgery charged the following payors for epidural steroid injections:

- a) Medicare;
- b) BlueCross BlueShield of Tennessee;
- c) United Healthcare;
- d) Tricare;
- e) Aetna;
- f) CIGNA;
- g) Humana;
- h) TennCare;
- i) uninsured patients; and
- j) patients paying out of pocket toward a deductible.

RESPONSE:

**OBJECTION.** This Interrogatory is overbroad, unduly burdensome, and seeks irrelevant information that is not reasonably calculated to lead to the discovery of admissible evidence.

Subject to and without waiving said objections, SSC has already provided billing statements to the Plaintiffs' counsel for the Plaintiffs' steroid injections which reflect the rate charged to the Plaintiffs and their insurers. The rates that SSC charges other insurers is not relevant to the claims forming the basis of the Plaintiffs' Complaints and is not reasonably calculated to lead to the discovery of admissible evidence.

VERIFICATION

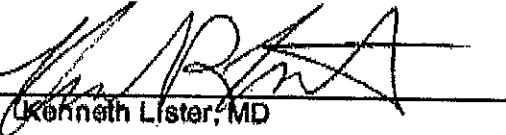
STATE OF TENNESSEE )

COUNTY OF DAVIDSON )

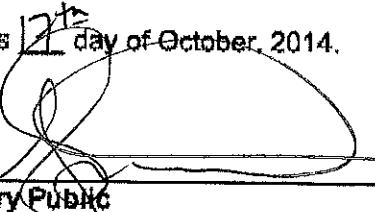
I, Kenneth Lister, MD, swear and affirm that:

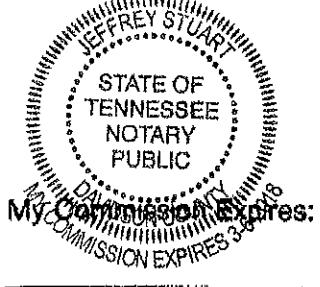
I was a member of Specialty Surgery Center, Crossville, PLLC from 2012 until its dissolution in 2014.

I have read the said interrogatories, and the foregoing answers thereto are true according to the best of my knowledge, information, and belief.

By:   
Kenneth Lister, MD

Sworn to and subscribed before me this 12<sup>th</sup> day of October, 2014.

  
Notary Public



✓25 NAC

Respectfully submitted,

**GIDEON, COOPER & ESSARY, PLC**

/s/ Chris J. Tardio

**C.J. Gideon, Jr.\***

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*Attorneys for SSC, Dr. Lister, and Dr.  
Lister's Practice*

\* Admitted pursuant to MDL Order No. 1.

\*\* Admitted *pro hac vice*.

CERTIFICATE OF SERVICE

I hereby certify that on the 27<sup>th</sup> day of October, 2014, a true and accurate copy of the foregoing was served on the PSC by hand-delivery and on the other parties below by serving a notice indicating that the PSC will upload the responses to the discovery repository in the MDL:

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<p>Frederick H. Fern Judi Abbott Curry Jessica Saunders Eichel Alan M. Winchester Harris Beach PLLC 100 Wall Street 23rd Floor New York, NY 10005</p>	
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/s/ Chris J. Tardio

**Chris J. Tardio**